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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/616,787 07/14/00 ENGLERT

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EXAMINER

HM12/0705

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ART UNIT

PAPER NUMBER

1655

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/616,787

Applicant(s)
Englert

Examiner
Arun Chakrabarti

Art Unit
1655



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 13, 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4and5 20) ☐ Other:

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DETAILED ACTION

Specification

1. Applicant has elected Group I, corresponding to claims 1-6, without traverse.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected as indefinite because the instantly claimed method lacks a final process step that clearly relates back to the preamble. For the method of claim 1, the preamble of the instantly claimed method is drawn to a method for multiplexed analysis of a plurality of target nucleic acid while the final process step is that of evaluating the presence of one or more capture sequence tags and it is thus unclear as to whether the instantly claimed methods are drawn to a method for multiplexed analysis of a plurality of target nucleic acid or rather evaluating the presence of one or more capture sequence tags. Method claim requires a last step or phrase in the last step that states the accomplishments of the goals for the method which were

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stated in the method's preamble. Claim 1 lacks such a last step and are confusing because the additional method step is not sufficiently set forth. While minute details are not required in method claims, at least the basic steps must be recited in a positive, active fashions. See *Ex parte Erlich*, 3 USPQ2d1011, p.1011 (Bd. Pat. Applicant. Int. 1986). It is suggested that an amended claim more clearly describing the intended steps be submitted.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

5. Claims 1-5 are rejected under 35 U.S.C. 102 (e) as being anticipated by Wong (U.S. Patent 5,935,793) (August 10, 1999).

Wong teaches a method for multiplexed analysis of a plurality of target nucleic acid sequences in a sample (Abstract) comprising the methods of:

providing, for each target nucleic acid sequence to be analyzed, at least one probe/primer molecule which probe/primer molecule includes a region of sequence substantially complementary to a sequence in the target nucleic acid sequence and a region that is not located

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at either terminus of the probe/primer and which includes a capture tag sequence (Abstract and Figures 1A and 1B and Column 5, line 49 to column 6, line 7 and Tables 1-3);

forming a reaction mixture which includes the probe/primer molecules and the target sequences under conditions such that, if a probe/primer molecule specific for a target sequence and the target sequences are both present, one or a plurality of derivative molecules having a capture tag at one or both its 3' or 5' termini, of the probe specific for the target sequence, is generated, thereby producing a derivative nucleic acid suitable for evaluation (Figure 4 and Examples 1 and 2);

evaluating the presence of one or more capture sequence tags (Figure 5 and Column 20, lines 47-60).

Wong teaches a method wherein the derivative nucleic acid molecules are analyzed by hybridizing the tag sequences to capture probes which are spatially separated (Figure 4 and Examples 1 and 2).

Wong inherently teaches a method wherein the capture probes are partially duplex probes with capture-tag-complementary single stranded overhangs (Table 2 and Column 24, lines 24-30).

Wong teaches a method wherein the capture tags are disposed on beads (Column 22, lines 7-12).

Wong teaches a method wherein the capture tags are disposed on an ordered array (Figures 3-5 and Examples 1-2).

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Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-6 are rejected under 35 U.S.C. 103 (a) over Wong (U.S. Patent 5,935,793) (August 10, 1999) in view of Zhang et al. (U.S. Patent 5,942,391) (August 24, 1991).

Wong teaches the methods of claims 1-5 as described above.

Wong does not teach the method wherein the derivative nucleic acid is ligated to a capture probe and then washed.

Zhang et al. teach the method wherein the derivative nucleic acid is washed and then ligated to a capture probe. (Column 40, lines 1-27 and Figure 5). However, MPEP 2144.04 further states, “*In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) Selection of any order of mixing ingredients is *prima facie* obvious”.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the washing and ligation steps of Zhang et al. into the method of Wong, since Zhang et al. state, “The beads were then washed twice with washing buffer to remove nonhybridized probes, as well as GnSCN, proteins, nucleic acids, and any potential PCR inhibitors (Column 40, lines 4-8).” By employing scientific reasoning, an

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ordinary artisan would have combined and substituted the washing and ligation steps of Zhang et al. into the method of Wong in order to improve the analysis of a plurality of target nucleic acid. An ordinary practitioner would have been motivated to combine and substitute the washing and ligation steps of Zhang et al. into the method of Wong, in order to achieve the express advantages noted by Zhang et al., of a method that provides removal of nonhybridized probes, as well as GnSCN, proteins, nucleic acids, and any potential PCR inhibitors.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Arun Chakrabarti,
Patent Examiner,



JEFFREY FREDMAN
PRIMARY EXAMINER

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June 26, 2001